

I Want The Kit: A Free Home-Based STI Testing (and Re-testing) Resource for Your Patients

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Maryland 2013 Annual STI Update
June 5, 2013

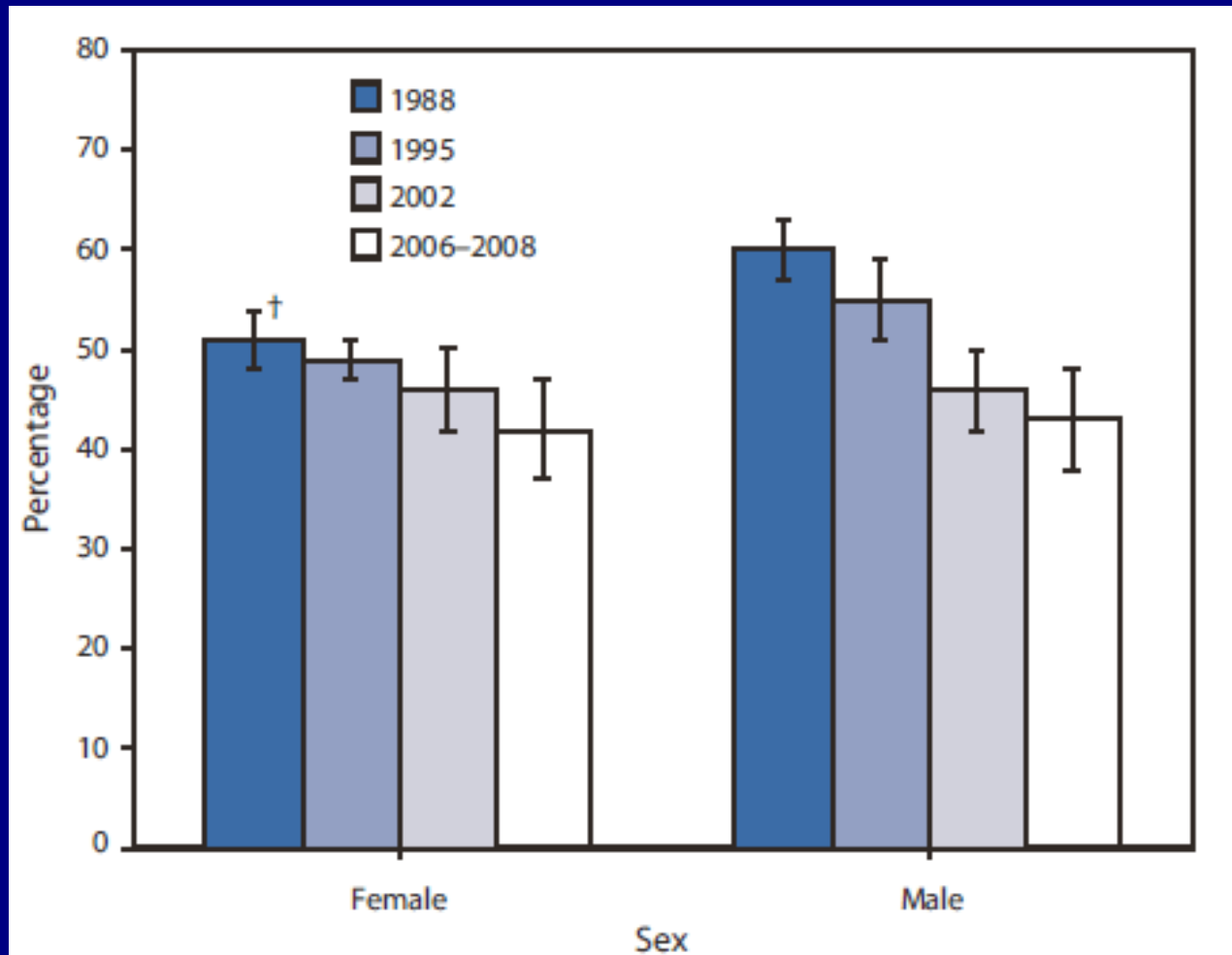
www.iwantthekit.org

<http://hopkinsmedicine.org/medicine/std>



Background

Never-Married Females and Males **Aged 15--19 Years**
Who Have Ever Had Sexual Intercourse*
National Survey of Family Growth, United States, 1988--2008



Baby Boomers at Risk for Sexually Transmitted Diseases

“A vigorous sex life for boomers carries the same risk as it does for younger people: sexually transmitted diseases....

Researchers point to a rise in the number of adults over 50 seeking treatment for such infections, including the virus that causes AIDS”



Updated Incidence and Cost Estimates New Prevalence Estimates

ORIGINAL STUDY

Sexually Transmitted Infections Among US Women and Men: Prevalence and Incidence Estimates, 2008

Catherine Lindsey Satterwhite, PhD, MSPH, MPH,† Elizabeth Torrone, PhD, MSPH,*
Elissa Meites, MD, MPH,* Eileen F. Dunne, MD, MPH,* Reena Mahajan, MD, MHS,*
M. Cheryl Bañez Ocfemia, MPH,* John Su, MD, PhD, MPH,*
Fujie Xu, MD, PhD,* and Hillard Weinstock, MD, MPH**

Prevalence: 110 M

Incidence: 19.7 M

ORIGINAL STUDY

The Estimated Direct Medical Cost of Selected Sexually Transmitted Infections in the United States, 2008

Kwame Owusu-Edusei Jr, PhD, PMP, Harrell W. Chesson, PhD,*
Thomas L. Gift, PhD,* Guoyu Tao, PhD,* Reena Mahajan, MD, MHS,†
Marie Cheryl Bañez Ocfemia, MPH,‡ and Charlotte K. Kent, PhD**

**Cost of incident
infections in 1 yr:
\$15.6 B**

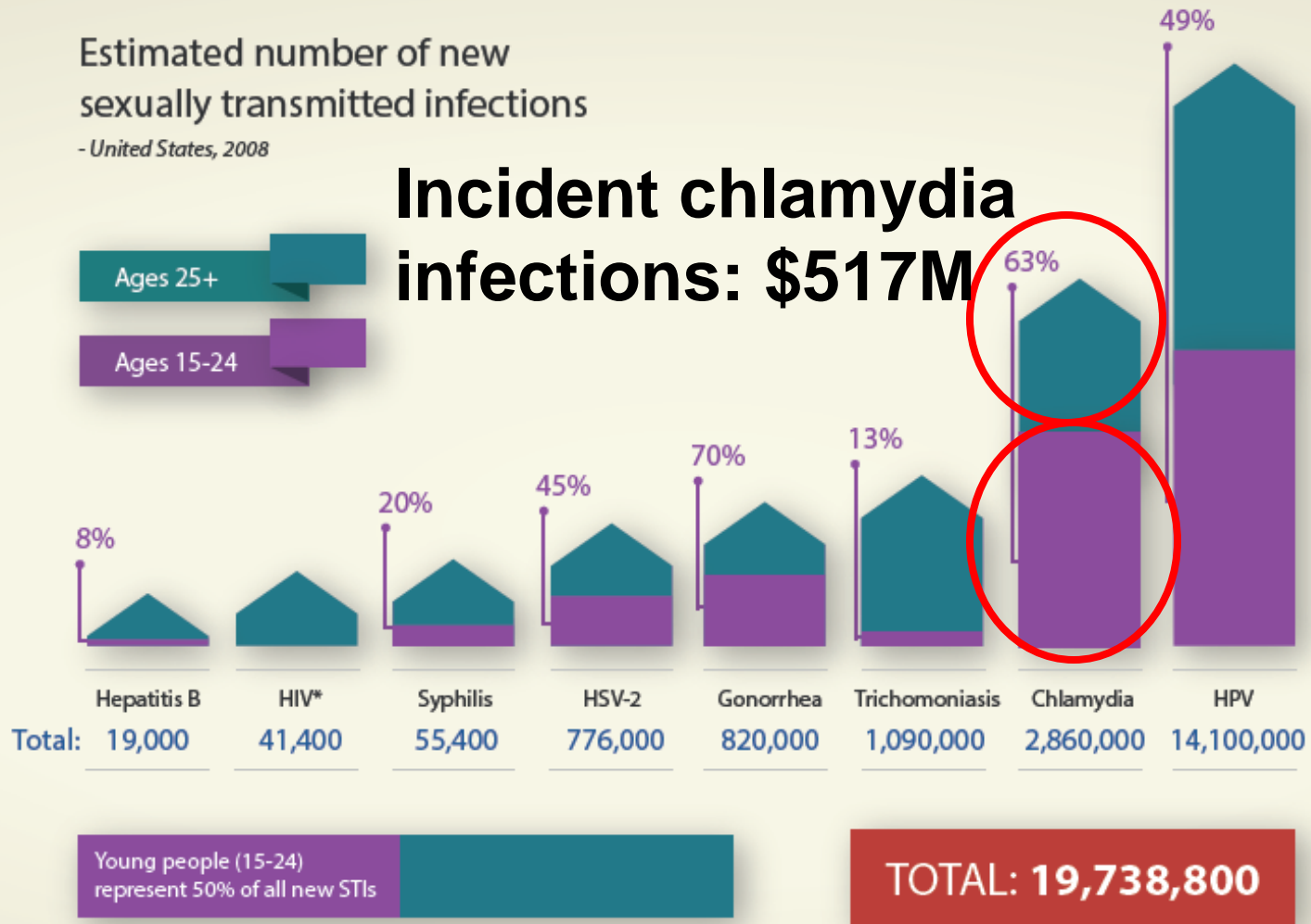
Satterwhite CL et al. Sexually Transmitted Diseases 2013;40:187-93.
Owusu-Edusei K Jr. et al. Sexually Transmitted Diseases 2013;40:197-201.

Incidence of STIs

Estimated number of new sexually transmitted infections

- United States, 2008

Incident chlamydia infections: \$517M



*HIV incidence not calculated by age in this analysis

Bars are for illustration only; not to scale, due to wide range in numbers of infections

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I Want The Kit - Male

I want the kit

« Women, click here to get started

Men, click here to get started »

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Totals for Internet 2004-2013

FEMALE Vaginal (N =4542) (2004)

CT:	prevalence	7.4%
GC	prevalence	0.9%
TV	prevalence	7.4%

MALE Penile (N = 2072) (2006)

CT:	prevalence	9.4%
GC	prevalence	0.9%
TV	prevalence	3.4%

FEMALE Rectal (N =623) (2009)

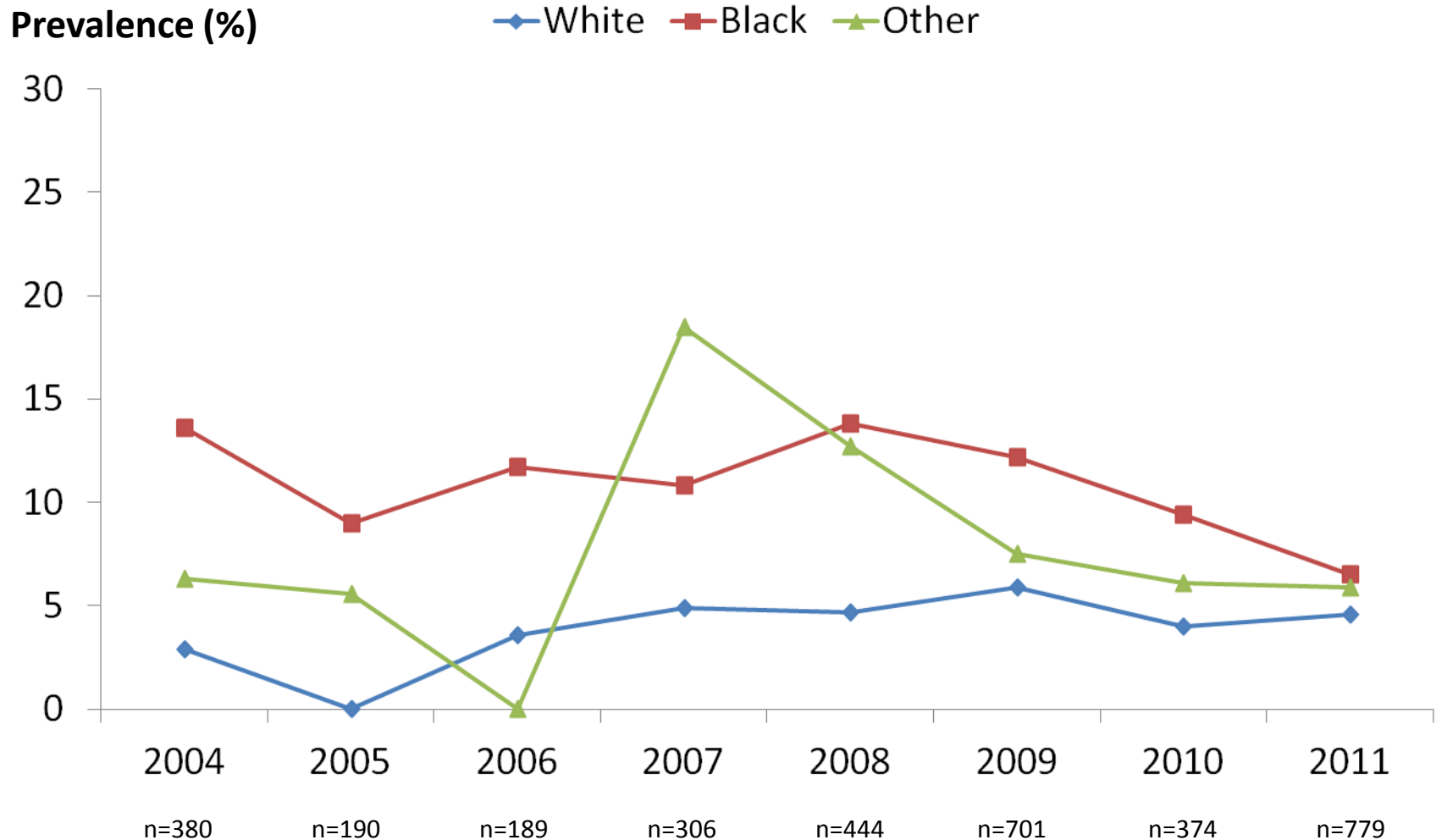
CT:	prevalence	8.7%
GC	prevalence	1.4%
TV	prevalence	6.1%

MALE Rectal (N = 290) (2009)


CT:	prevalence	6.9%
GC	prevalence	4.8%
TV	prevalence	0.69%



Chlamydia Prevalence of 3363 Female Internet STD Screening Program Participants by Race, Calendar Year



Texting Return of Results for Internet

- Since September 2010, 1,545 negative results have been returned by texting
- IWTK is Clear  IWTK is negative

Yearly Internet Tests

Kits requested: **2011:** **3,572**
 2012: **3,599**

	Vaginal	Female Rectal	Penile	Male Rectal	Total
Total 2011	749	155	421	103	1515
Total 2012	961	221	572	99	1853

Return rate: **2004-7 ~30%; 2011: 42.4%;**
 2012: 51.5%; 2013: 57.5% (Jan-Mar)

Outline: What is new for IWTK?

- Update of website IWTK to modernize and allow secure login to retrieve own results
- Risk quiz: Tallied risk scores and test results
- Cost effectiveness study IWTK NAAT vs. Clinic IWTK Test
 - Self-collected rectal swabs
 - Dry transport of swabs for CT, GC, TV
 - Penile swabs compared to urines
- Repeat tests data for females
 - Male trichomonas paper

IWTK Home Page

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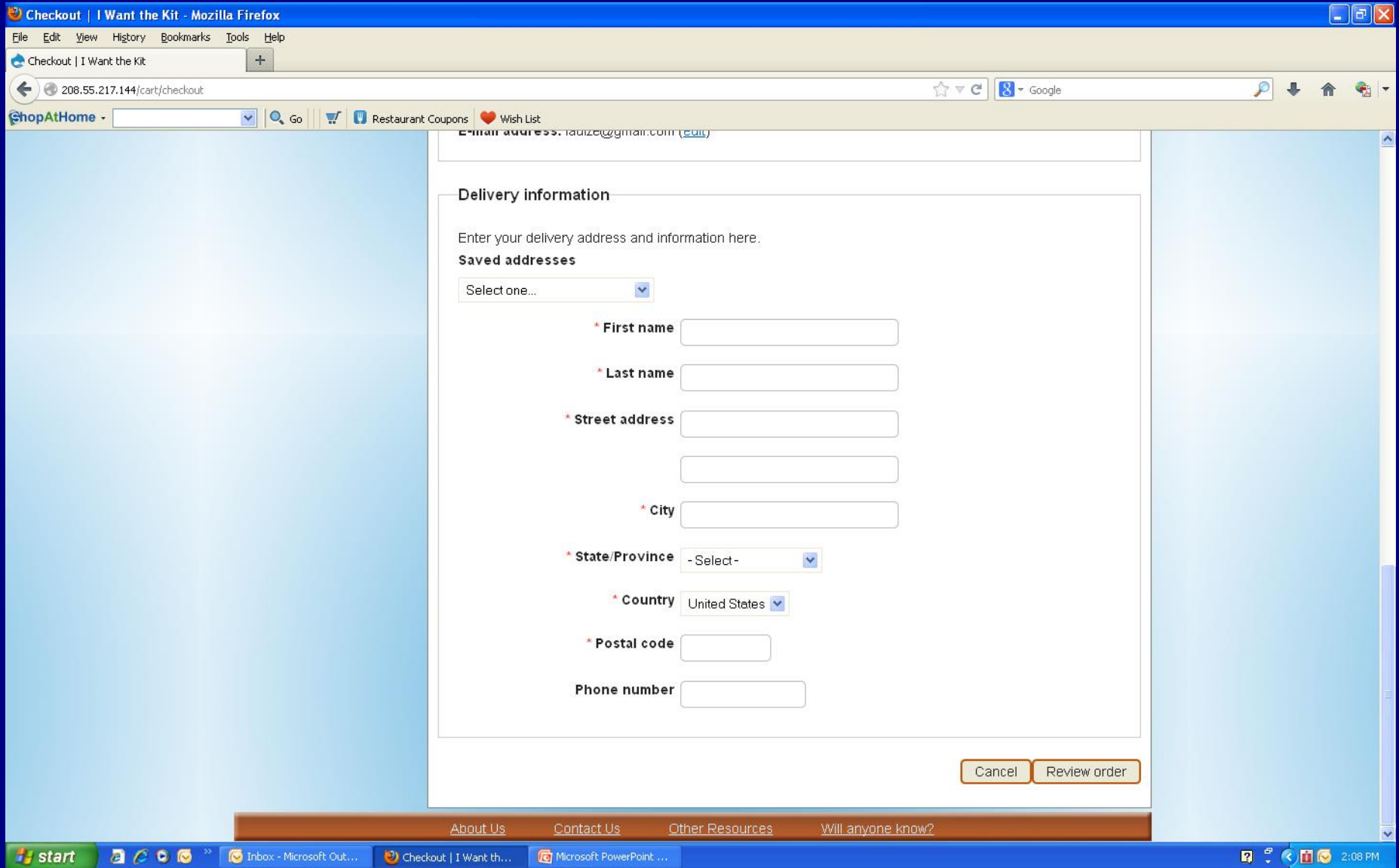
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New IWTK Website Features

- Secure password protected log in
- Selection of clinic before ordering kit
- New instructions and video of instructions
- Text to notify user that kit was mailed, received, and “results ready” to be retrieved
- New information about STIs





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[Syphilis](#)

[Bacterial Vaginosis \(BV\)](#)

[Human Papilloma Virus \(HPV\)](#)

Home

Kit Order Detail

Kits can only be delivered to Maryland, Washington D.C. and Alaska.

- Select -

Allegany - 12501 Willowbrook Rd, Cumberland, MD 21502: (301)-759-5082

Anne Arundel - 1 Harry S Truman Parkway, Suite 200, Annapolis, MD 21401: (410)-222-7382 *Cost: \$30.00

Baltimore County - 6401 York Road, 3rd FL Baltimore, MD 21212: (410)-887-3740

Baltimore City - 210 Guilford Avenue, 3rd Floor- Baltimore, MD 21202: (410)396-4448

Calvert - 975 Solomons Island Rd North, Prince Frederick, MD 20678: (410)-535-5400

Caroline - 403 South 7th Street, Denton, MD 21629: (410)-479-8000

Carroll - 290 South Center Street, Westminster, MD 21157: (410)-876-4770

Cecil - 401 Bow Street, Elkton, MD 21921: (410)-996-5100

Charles - 4545 Crane Highway, White Plains, MD 20695: (301)-609-6900

Dorchester Co. - 3 Cedar Street, Cambridge, MD 21613: (410)-228-3223

Frederick - 350 Montevue Lane, Frederick, MD 21702: (301)-600-1733

Garrett - 1025 Memorial Drive, Oakland, MD 21550: (301)-334-7770

Harford - 1321 Woodbridge Station Way, Edgewood, MD 21040: (410)-612-1779

Howard - 7180 Columbia Gateway Dr. Columbia, MD 21046: (410)-313-7524

Kent - 125 S. Lynchburg Street Chestertown, MD 21620: (410)-778-1350

Montgomery - 2000 Dennis Avenue, Rm 107, Silver Spring, MD 20902: (240)-777-1760 *Cost: \$10.00 Donation

Prince George's - 3003 Hospital Drive, Suite 3048 Cheverly, MD 20785: (301)-583-3150 *Cost: \$10.00 Donation

Queen Anne's - 206 North Commerce Street Centreville, MD 21617: (410)-758-0720

St. Mary's - 21580 Peabody Street, Box 316, Leonardtown, MD 20650: (301)-475-4330

- Select -

You must select a treatment center prior to ordering a kit

Type of kit *

☐ Male (Penile)

☐ Female (Vaginal)

☐ Rectal (Anal)

NOTE: If you are transgendered, please select the kit that reflects your current anatomy

start

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Female Testing Kit Contents



Contact Form (Keep second copy for your use)

Kit Number: _____

Name: _____

Address: _____

Contact method (in case we need to contact you):

Check all that apply:

☐ Cell phone

☐ US Mail

You will receive an email or text when your results are ready.

Maryland and DC Residents:
Local (Baltimore): 410-955-9764
Toll-free: 800-675-5504

Markkula Baran
Johns Hopkins Building 530
855 N Wolfe St
Baltimore, MD 21205

UN3373

Markkula Baran
Johns Hopkins Building 530
855 N Wolfe St
Baltimore, MD 21205

DO NOT BEND OR FOLD

Low Risk:

Please don't send this sheet back
sample(s) Please keep it for you

Please do not return this form with your Specimen

What's Your Risk of Having an STI? This sheet is for your private record.

If you ever had any type of sexual intercourse (vaginal sex, oral sex, or anal sex), please take the following optional and private risk questionnaire. You can fill out the questionnaire at home and bring it to the clinic. If taking the risk quiz with the contact form, question 3, and then place it in the postage paid return envelope and drop it in the mailbox.

1. Are you <25 years old? Yes ☐ No ☐
2. Have you ever had sex with a new partner? Yes ☐ No ☐

Female Testing Kit
READ ALL INSTRUCTIONS BEFORE YOU START

Women: We need like you to collect a vaginal sample by inserting a sterile swab into your vagina. You will receive a yellow contact form, and instructions for collecting a vaginal sample.

form that consists of duplicate pages. Place the form in your kit and keep the back page for you.

Follow the steps below. A diagram showing the correct way to use the swab is provided. Before opening the swab, go to a toilet (sitting on the toilet seat or standing). Undress from the waist down and insert the swab into the vagina. If you are pregnant or are having

problems, the swab is attached to cap.

Insert the swab into the opening of your vagina and make sure that it touches the walls of the vagina.

Place the swab back into the tube closing it securely.

Put the tube in the plastic Ziploc bag.

Seal the bag, and the first page of the yellow contact form, and drop into any mailbox.

You will be asked to give your password and kit number to receive your results.

The Chlamydia Self-Test



Self-Collection of Vaginal Swab

ATTENTION: Read ALL instructions before you begin!

STEP 1



Wash your hands thoroughly.

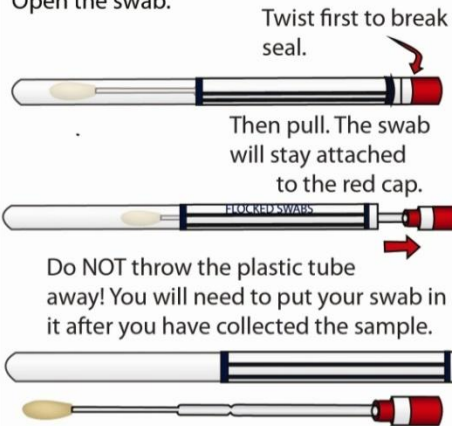
STEP 2



Undress from the waist down. Get into a position where you can comfortably insert a swab into your vagina- such as sitting on the toilet, or standing with one foot on a chair, or any position that you would use to insert a tampon.

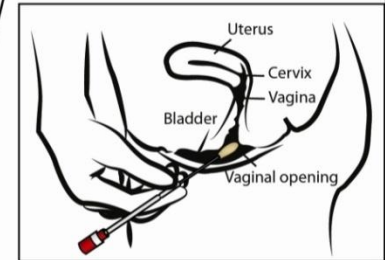
STEP 3

Take the sealed swab out of the package. Open the swab.



STEP 4

Insert the white tip of the swab about one inch inside the opening of your vagina.



STEP 5

Rotate the swab for 15 seconds, making sure that the swab touches the walls of your vagina so that moisture is absorbed into the swab.



STEP 6

Remove the swab from your vagina. Don't let the tip of the swab touch anything else.

STEP 7

Place used swab back into the transport tube. Close tightly to prevent leakage.



STEP 8

Place closed tube into the red plastic zip-lock bag. Seal the bag.



STEP 9

Place sealed zip-lock bag into the return mailer (yellow envelope). Seal the envelope and drop it in any mailbox. It's already addressed and postage is paid, so you don't need to do anything else.



Self-Collection of Penile Swab

ATTENTION: Read ALL instructions before you begin!

STEP 1

Take the sealed swab out of the package.
Open the swab.

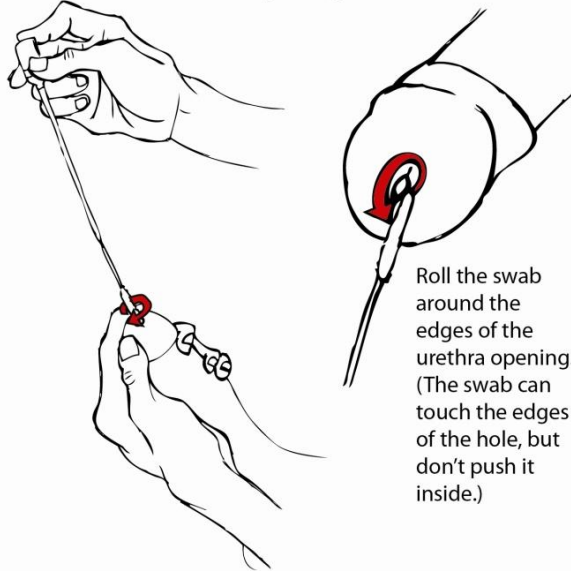
Twist first to break
seal.

Then pull. The swab
will stay attached
to the red cap.

Do NOT throw the plastic tube
away! You will need to put your swab in
it after you have collected the sample.

STEP 2

Roll the swab just at the tip or inside the opening to
the penis through which you pass urine (pee). Roll the
swab completely around the opening to get the best
specimen. It is not necessary to put the swab deep
inside the hole (urethra opening).



Roll the swab
around the
edges of the
urethra opening.
(The swab can
touch the edges
of the hole, but
don't push it
inside.)

STEP 7

Place used swab back into the transport tube. Close tightly
to prevent leakage.



STEP 8

Place closed tube into the red plastic zip-lock bag. Seal the bag.



STEP 9

Place sealed zip-lock bag into the return mailer (yellow
envelope). Seal the envelope and drop it in any mailbox. It's
already addressed and postage is paid, so you don't need to
do anything else.



Self-Collection of Rectal Swab

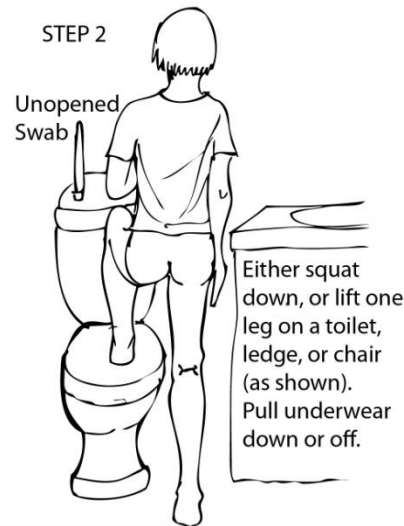
ATTENTION: Read ALL instructions before you begin!

STEP 1



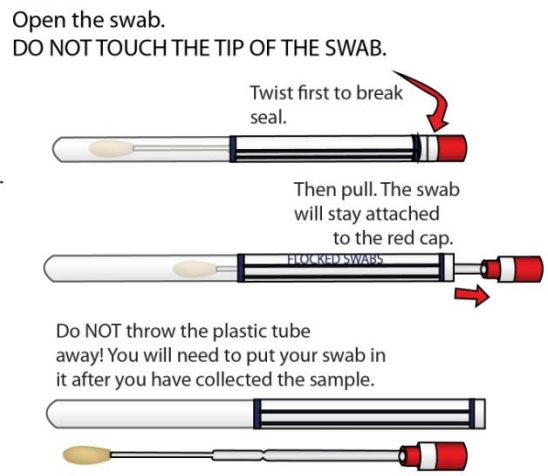
Wash your hands thoroughly.

STEP 2



Either squat down, or lift one leg on a toilet, ledge, or chair (as shown). Pull underwear down or off.

STEP 3



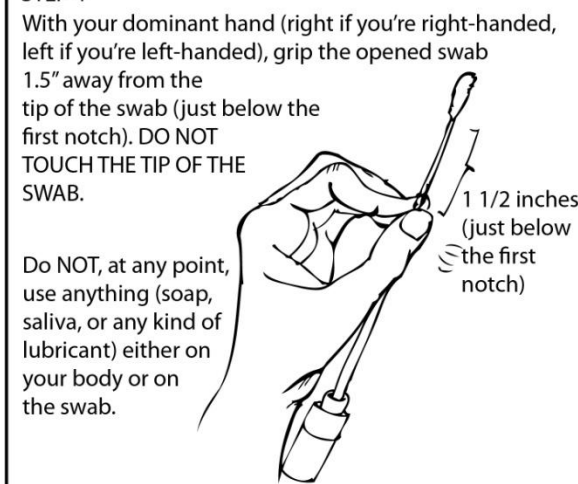
Open the swab.
DO NOT TOUCH THE TIP OF THE SWAB.

Twist first to break seal.

Then pull. The swab will stay attached to the red cap.

Do NOT throw the plastic tube away! You will need to put your swab in it after you have collected the sample.

STEP 4

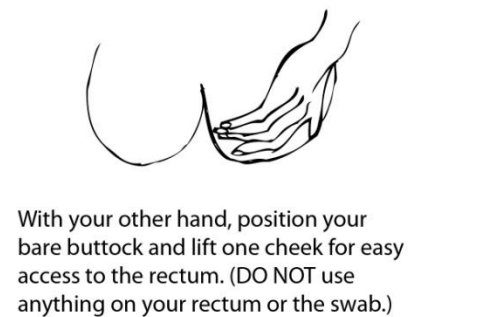


With your dominant hand (right if you're right-handed, left if you're left-handed), grip the opened swab 1.5" away from the tip of the swab (just below the first notch). DO NOT TOUCH THE TIP OF THE SWAB.

Do NOT, at any point, use anything (soap, saliva, or any kind of lubricant) either on your body or on the swab.

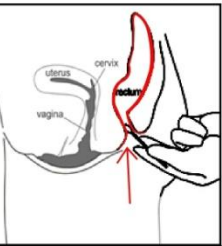
1 1/2 inches (just below the first notch)

STEP 5

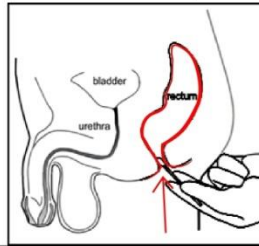


With your other hand, position your bare buttock and lift one cheek for easy access to the rectum. (DO NOT use anything on your rectum or the swab.)

Female Anatomy



Male Anatomy



STEP 6
Insert the swab 1.5 inches into your rectum until you feel your fingers touch your anus.

STEP 7
Once the swab is in, walk your fingers halfway down the swab (away from your body) and grip it there, for stability. (The swab should stay where it is—only your fingers should move.)

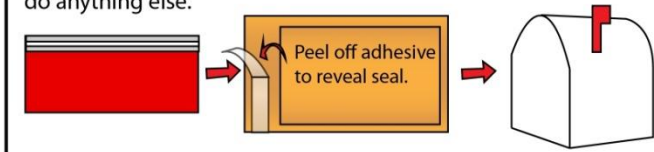
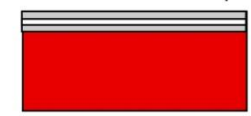
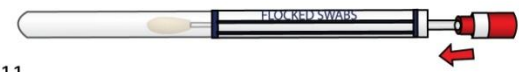
STEP 8
Gently rub the swab in a circle, touching the walls of your rectum, to collect the specimen.

STEP 9
When removing the swab from your rectum, slowly turn it in a circle while pulling it out.

STEP 10
Place used swab back into the transport tube. Close tightly to prevent leakage.

STEP 11
Place closed tube into the red plastic zip-lock bag. Seal the bag.

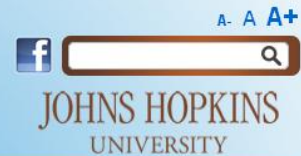
STEP 12
Place sealed zip-lock bag into the return mailer (yellow envelope). Seal the envelope and drop it in any mailbox. It's already addressed and postage is paid, so you don't need to do anything else.



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What are STI's?



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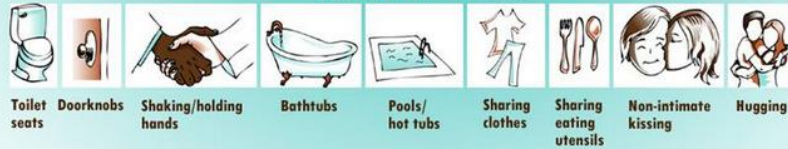
What are STIs?

STIs, or sexually transmitted infections, are passed from person to person through sex. Sex is putting the penis into the vagina, rectum or mouth; and/or putting the mouth on the penis, vagina or rectum. You cannot get STIs through casual contact.

An older term for STIs is STDs, or sexually transmitted diseases.

Click on the links to the left to find out more about each STI.

You **CAN'T** get STIs from:



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Order Processing

Ship to:
JANE DOE
555 ESKIMO WAY
ANCHORAGE, DC 21223

Kit Order Detail:

Confirm your date of birth:	11/12/1989
Confirm your state:	Alaska
Clinic center:	Please call our toll free number (866) 575-5504
Type of kit:	Female (Vaginal)

Order comments:

Date	Status	Message
05/24/2013	-	Order created.

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- Syphilis
- Bacterial Vaginosis (BV)
- Human Papilloma Virus (HPV)

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Kit Shipped

Ship to:

JANE DOE
555 ESKIMO WAY
ANCHORAGE, DC 21223

Kit Order Detail:

Confirm your date of birth:

11/12/1989

Confirm your state:

Alaska

Clinic center:

Please call our toll free number (866) 575-5504

Type of kit:

Female (Vaginal)

Order comments:

Date	Status	Message
05/24/2013	-	Order created.
05/24/2013	Shipped	-

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- Chlamydia
- HIV/AIDS
- Gonorrhea
- Hepatitis B
- Trichomoniasis
- Herpes Simplex Virus (HSV)
- Syphilis
- Bacterial Vaginosis (BV)
- Human Papilloma Virus (HPV)

Result Available

Ship to:

JANE DOE
555 ESKIMO WAY
ANCHORAGE, DC 21223

Kit Order Detail:

Confirm your date of birth:

11/12/1989

Confirm your state:

Alaska

Clinic center:

Please call our toll free number (866) 575-5504

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Female (Vaginal)

Order comments:

Date	Status	Message
05/24/2013	-	Order created.
05/24/2013	Shipped	-
05/24/2013	Result Available	-

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Outline: What is new for IWTK?

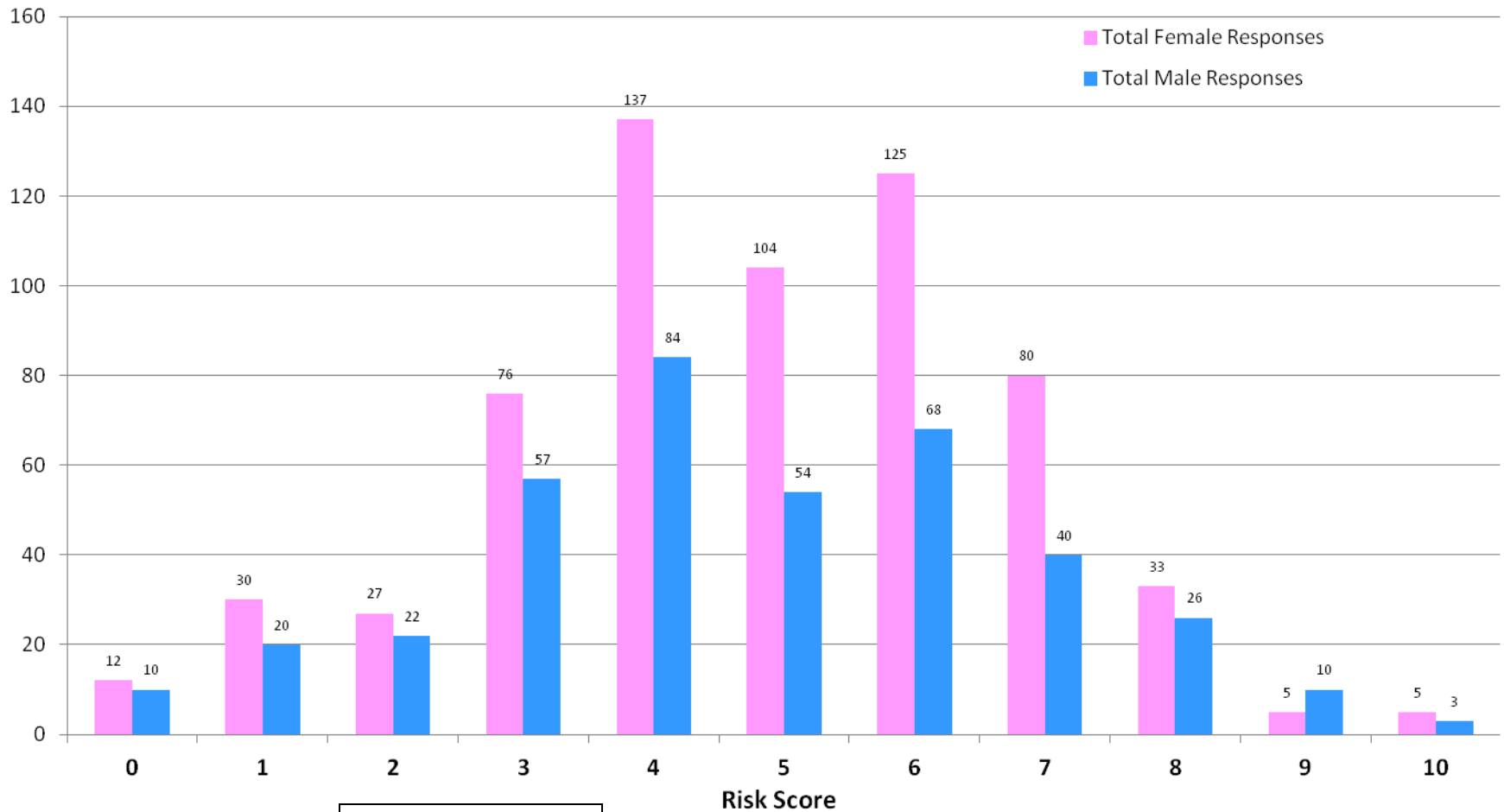
- Update of website IWK to modernize and allow secure login to retrieve own results
- Risk quiz: Tallied risk scores and test results

Risk Quiz (Nov 2010)

1. Are you ≤ 25 years old? Yes (1) No
2. Have you had either (or both) a new sex partner or multiple partners in the last 90 days? Yes (1) No
3. Do you have more than one current sex partner at the present time? Yes (1) No
4. Have you ever been told you had or been treated for a sexually transmitted infection in the past? Yes (1) No
5. How many sex partners have you had in the last 90 days?
0-1 (0) 2-4 (1) 5-9 (2) 10 or more (3)
6. When you have sex do you use a condom?
Always (0) Sometimes (3) Never (3)

Score: 0-1 Low risk; 2-3 Intermediate; 4-6 High Risk; 7-10 Very High Risk

IWTK - # of Returned/Tested Kits with Risk Scores- Females vs. Males (N = 1,028)



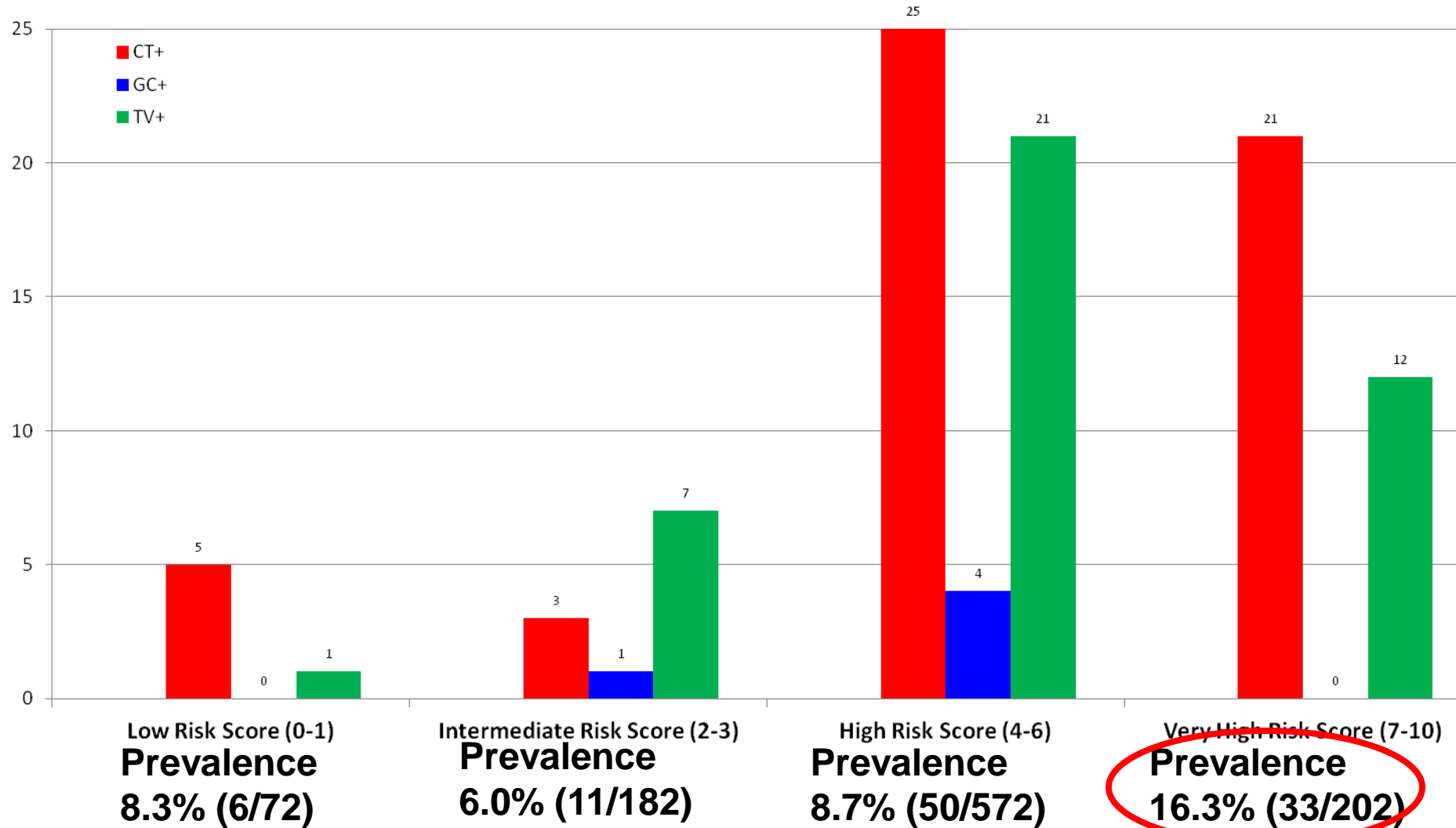
Low 7.0%

**Intermediate
17.7%**

High 55.6%

Very High 19.6%

IWTK - Risk Scores & Returned/Tested Kits with Positive Results - Male & Female Combined (total prevalence 9.72%)



Outline: What is new for IWTK?

- Update of website IWTK to modernize and allow secure login to retrieve own results
- Risk quiz: Tallied risk scores and test results
- **Cost effectiveness study IWTK NAAT vs. Clinic IWTK Test**

Internet more cost-effective than Clinics

Cost-effectiveness Analysis of *Chlamydia trachomatis* Screening Via Internet-based Self-collected Swabs Compared With Clinic-based Sample Collection

Wei Huang, MS,* Charlotte A. Gaydos MS, MPH, DrPH,† Mathilda R. Barnes, MS,† Mary Jett-Goheen, BS,† and Diane R. Blake, MD‡

Background: Although the Centers for Disease Control and Prevention have recommended population-wide *Chlamydia trachomatis* screening of sexually active women less than 26 years of age, more than half of sexually active young women are not routinely screened. A Website (IWTK, www.iwantthekit.org), was developed in 2004 to promote home-based sample collection.

Methods: A decision tree was designed to model a hypothetical cohort of 10,000 women per year who order an internet-based *C. trachomatis* screening kit. We compared the incremental cost-effectiveness of 2 screening strategies: self-sampling via the IWTK website, and traditional, clinic-based screening by the same cohort of women who used IWTK. Probabilities and costs were estimated for each node in the decision tree. Estimates were derived from primary data, published data, and unpublished health data.

Results: The internet-based screening strategy prevented 35.5 more cases of pelvic inflammatory disease and saved an additional \$41,000 in direct medical costs as compared with the clinic-based screening strategy.

Conclusion: Our model estimates demonstrated that an internet-based, self-swab screening strategy was cost-effective compared with the traditional, clinic-based screening strategy. Assuming that the popularity of the use of the internet as a resource for information about healthcare and sexually transmitted infections leads to an increased use of IWTK, the public health benefit of this cost-effective strategy will be even greater.

Ct infections in women are asymptomatic.² Untreated Ct infection can progress, giving rise to serious and costly sequelae for women, including pelvic inflammatory disease (PID), infertility, ectopic pregnancy, and chronic pelvic pain.^{3,4} With the advent of highly specific and sensitive nucleic acid amplification tests, noninvasive improved detection and treatment of Ct infection is possible.⁵

The Centers for Disease Control and Prevention (CDC) have recommended population-wide screening of sexually active women aged <26 years.² Although the annual Ct screening rate increased from 25.3% in 2000 to 41.6% in 2007,¹ and many studies have shown that Ct screening in women is cost-effective,^{6–8} more than half of sexually active young women with a health insurance plan are not routinely screened in clinics.¹ Moreover, many women who meet CDC guidelines are not screened at publicly funded clinics due to budgetary constraints,⁹ and screening is even less frequent in private practice settings.¹⁰ As adults and adolescents are increasingly using the internet to search for information about healthcare and STIs,¹¹ this resource holds great promise as a means of increasing Ct screening. Many women prefer to screen for STIs at home, and when given this opportunity, are more likely to obtain screening as compared with those women whose only option is clinic-based screening (64.6% vs. 31.6%).¹² Accordingly, the use of home-based sample collection may signifi-

Internet More Cost-effective than Clinics

Decision tree to model hypothetical cohort of 10,000 women

Strategy	CT Cases	Total cost	Incremental cost	PID Expected	Incremental PID Averted	Cost/case PID Averted (ICER)
Internet	303	\$860K	-	179.9	35.5	-
Clinic	232	\$902K	\$41K	215.4	-	-1155*

*Internet strategy saves \$1155 per additional case PID averted

ICER, Incremental cost-effectiveness ratio

Huang W, Gaydos CA, Barnes MR, et al. Sex Transm Dis, 38:815-820, 2012

Outline: What is new for IWTK?

- Update of website IWTK to modernize and allow secure login to retrieve own results
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- Self-collected rectal swabs

Internet Rectal Kits- Females

- From 1,084 women submitting vaginal swabs 2009-11 to IWTK , **17.9%** reported anal intercourse (AI) last 90 days.
- **113 (58.2%)** returned rectal kits; **95** additional kits were returned by women not reporting recent AI
- Total of 406 rectal kits ordered by women overall, 208 (51.2%) were returned; **205 were tested.**
- Of tested, (18.5%) were rectal positive: CT 12.7%, NG 2.4%, TV 6.3%; 5 coinfectd
- Women also returned vaginal swabs, (70.5%) were positive for at least one of the three STIs vaginally
- 36.8% positive women not diagnosed if only vaginal kit

Characteristics of 205 Rectal IWTK Female Users

Characteristics	Categories	Mean or Percentage
Age	Years	25.8 yr.
Race	African American/White	50.0%/42.4%
Marital Status	Single	91.2%
Education	Bachelors +	28.0%
Anal sex	Last 3 months	57.5%
New Anal PN	Last 3 months	19.8%
High Risk Sex Behaviors	Never used condoms AI	48.7%
	Always uses condoms AI	14.0%
	PN ever had STD	33.5%
	Forced Anal Sex	57.5%
	Drink before Sex	57.9%

Rectal Results (multivariate logistic regression)

		OR	p-value	AOR	p-value
CLINICAL INDICATORS					
Vaginal STI	Neg	Ref		Ref	
	Pos	33.60**	<.001	37.62**	<.001
Rectal Symptoms	No	Ref		Ref	
	Yes	1.11	.806	0.43	.213
DEMOGRAPHICS					
Age (per yr)		0.92*	.015	0.95	.171
Marital Status	Single	Ref		Ref	
	Married	0.26	.202	0.41	.407
Race/Ethnicity	White non-Hispanic	Ref		Ref	
	Black non-Hispanic	3.53**	.007	3.14*	.015
Health Insurance	No	Ref		Ref	
	Yes	0.78	.514	0.78	.590
Medicaid Eligible	No	Ref		Ref	
	Don't know	2.52*	.036	1.41	.493
	Yes	2.34	.136	1.04	.956

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- Self-collected rectal swabs
- Dry transport of swabs for CT, GC, TV



Can mailed swab samples be dry-shipped for the detection of *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Trichomonas vaginalis* by nucleic acid amplification tests? ☆

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ABSTRACT

Dry-shipped and mailed vaginal swabs collected at home have been used in research studies for the detection of *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (GC), and *Trichomonas vaginalis* (TV) by nucleic acid amplification tests (NAATs) in screening programs. A verification study was performed to compare the limit of detection of CT, GC, and TV on swabs that were dry-shipped to paired swabs that were wet-shipped in transport media through the US mail. The Centers for Disease Control and Prevention prepared inocula in sterile water to mock simulated urogenital swabs with high to low concentrations of CT and GC. Replicate swabs were inoculated with 100 µL of dilutions and were dry transported or placed into commercial transport media ("wet") for mailing for NAAT testing. The University of Alabama prepared replicate concentrations of TV, which were similarly shipped and tested by NAAT. All paired dry and wet swabs were detectable for CT. For GC, all paired dry and wet swabs were detectable for GC at concentrations $\geq 10^3$. At 10^2 and 10 CFU/mL, the 10 replicate GC results were variably positive. For TV, wet and dry shipped concentrations $>10^2$ TV/mL tested positive, while results at 10 TV/mL were negative for dry swabs. Holding replicate dry swabs at 55°C 5 days before testing did not affect results. NAATs were able to detect CT, GC, and TV on dry transported swabs. Using NAATs for testing home-collected, urogenital swabs mailed in a dry state to a laboratory may be useful for outreach screening programs.

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 - Self-collected rectal swabs
- Dry transport of swabs for CT, GC, TV
- Penile swabs compared to urines

SHORT REPORT

Comparison of self-obtained penile-meatal swabs to urine for the detection of *C. trachomatis*, *N. gonorrhoeae* and *T. vaginalis*

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ABSTRACT

Background Self-obtained penile-meatal swabs and urine specimens have been used for *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (NG) and *Trichomonas vaginalis* (TV) for outreach screening in men.

Objective To compare the sensitivity of self-collected male penile-meatal swabs and urine for the detection of CT, NG and TV.

Methods Matching penile-meatal swabs and urines were collected at home after recruitment to the study; via the internet programme, <http://www.iwantthekit.org>. The instructions directed the participant to place the tip of a Copan flocked swab at the meatal opening of the urethra to collect the penile-meatal sample. Two ml of urine was collected after the swab onto a Copan sponge-on-a-shaft collection device. Both swab and urine were placed into individual Aptima transport media tubes and mailed to the laboratory for testing. All specimens were tested for CT and NG using the GenProbe Aptima Combo2 Assay and for TV using GenProbe Aptima Analyte Specific Reagents with TV oligonucleotides.

Results Of 634 men, 86 (13.6%) were positive for CT, 9 (1.4%) were positive for NG and 56 (9.3%) positive for TV. For CT, swab sensitivity was 81/86 (94.2%), and urine sensitivity was 66/86 (76.7%). For NG, swab sensitivity was 9/9 (100%) and urine sensitivity was 8/9 (88.9%). For TV, swab sensitivity was 45/56 (80.4%) and urine sensitivity was 22/56 (39.3%).

Conclusions Self-obtained penile-meatal swabs provided for the detection of more CT, NG and TV, than urine specimens.

has shown feasibility for testing home-collected specimens for STIs in men and women.^{5–6} Our objective was to compare the sensitivity of self-collected penile-meatal swabs and urines for the detection of *C. trachomatis* (CT), *Neisseria gonorrhoeae* (NG), and *Trichomonas vaginalis* (TV) in men.

METHODS

From September 2006–November 2009, 634 men requested and submitted home collection kits for CT, NG and TV testing via <http://www.iwantthekit.org>. Participants were instructed to collect specimens as previously described.⁶ Specimens were tested for CT and NG using GenProbe APTIMA Combo2 transcription-mediated amplification, according to manufacturer's instructions, and for TV using GenProbe APTIMA Analyte Specific Reagents with TV oligonucleotides. The cutoff for positive specimens for TV was >60 000 relative light units.⁷ Discordant urine and swab results were tested for CT and NG using GenProbe APTIMA standalone assays, APTIMA *Chlamydia trachomatis* (ACT) or APTIMA *Neisseria gonorrhoeae* (AGC). Discordant testing was not performed for TV.

'Infected patient status' for CT and NG were those who had two positive results by GenProbe Combo2 (urine and swab) or were ACT/AGC positive when specimens were discordant. In the case of TV, any positive specimen result was considered a true positive. This assay had been defined previously as highly sensitive and specific.⁷ The study was approved by the Johns Hopkins University Institutional Review Board and written consent was obtained from participants.

INTRODUCTION

In the USA, 18 million new cases of sexually trans-

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 - Self-collected rectal swabs
 - Dry transport of swabs for CT, GC, TV
 - Penile swabs compared to urines
- Repeat tests data for females

Repeat Female Tests on the Internet

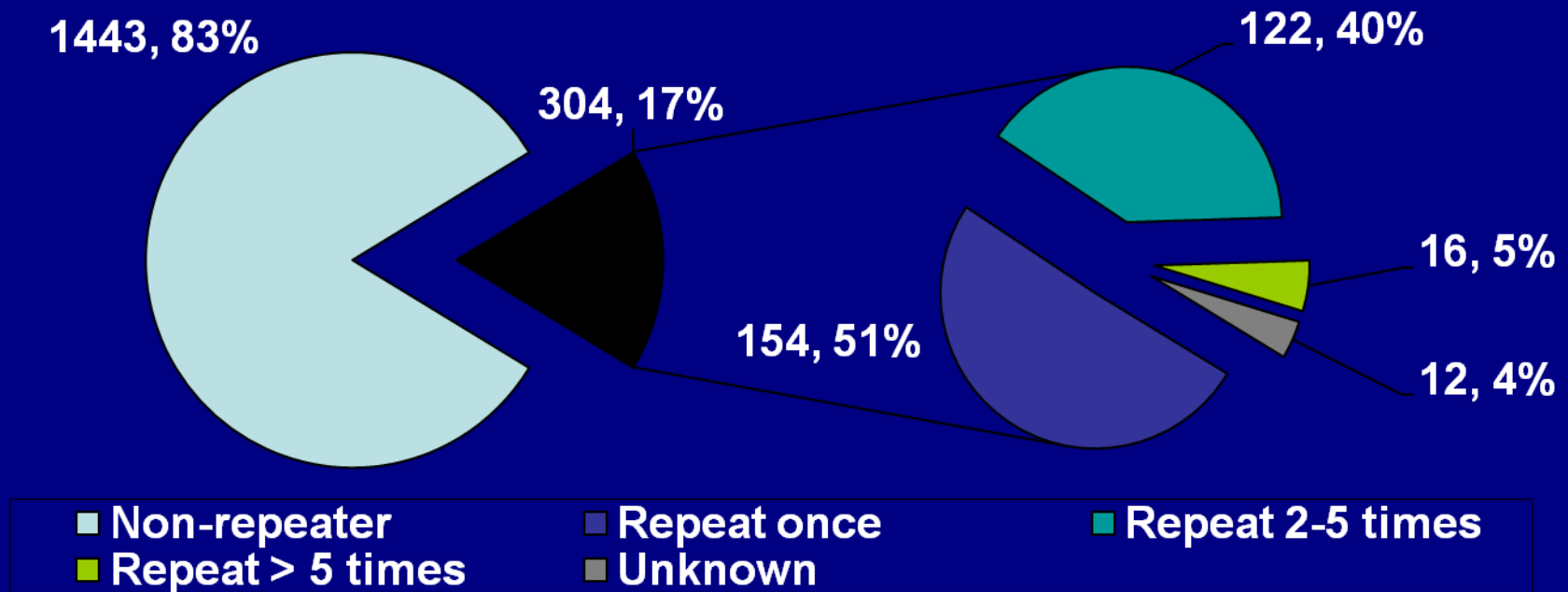
- Characteristics (demographics, risk behaviors, use perceptions) of repeat users were determined from questionnaires.
- Predictors of repeat users were measured in a matched case-control study by conditional logistic regression analysis. A case (N=304) was defined as reporting having ever used IWTK before.
- A control was a user who reported never using the program earlier. Two controls (N=608) were systematically sampled for each case by matching date of use of IWTK of the case within 3 months.

Repeat Female Tests

- CDC recommends repeat testing of infected women after 3 months
- From 2007-2010, 1,747 women indicated whether they had used IWTK previously
- 304 (17.3%) women used the Internet previously
- Of these:

1 more time	50.7%,
2-5 times	40.1%
> 5 times-	5.2%
Missing:	3.9%

Repeat Female Tests

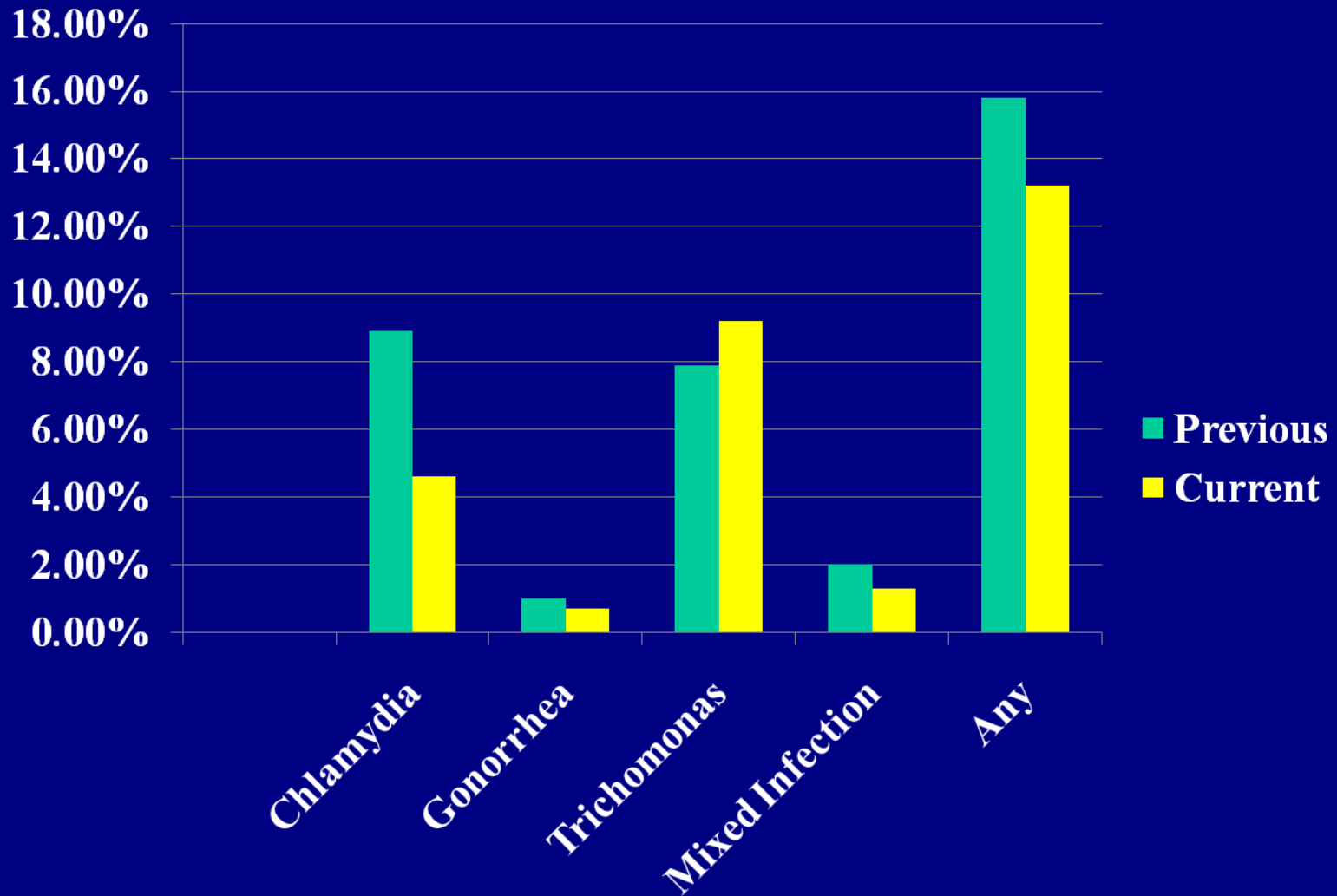


- Of repeat users, 84.2% reported having a negative prior test and 48/304 (15.8%) reported previous test positive
- At present test, 40 (13.2%) were positive
- Previous TV was associated with current TV positivity ($p < 0.05$)

Characteristics of 304 Repeat IWTK Female Users

Characteristics	Categories	Mean or Percentage
Age	Years	24.7 ± 5.7 yr.
Race	African American	69%
Marital Status	Single	87%
Education	Some college and above	61%
Repeat IWTK Use	> 2 times	45%
Current GU symptoms		60%
High Risk Sex Behaviors	Never used condoms	13%
	Anal Sex last 3 mo	16%
	2-4 partners in the past year	57%
	New partners in last 3 mo	44%
	Having sex >1 person currently	32%
	Having been treated for STI	77%

Repeat Female Tests (N = 304)



Factors Associated with 304 Repeat IGTK Female Users

Characteristics	Categories	OR (95% CIs)
Age	< 20 years	2.10 (1.30, 3.38)
	≥ 20 years	1.00
Had a Pelvic Exam in last yr.	Yes	2.03 (1.36, 3.05)
Perceived Internet Test Confidential	Yes	1.98 (1.32, 2.97)
Ever Been Treated for an STI	Yes	2.32 (1.57, 3.44)
Perceived Self-Swabs as Accurate	Yes	2.49 (1.61, 3.87)
Ever Been Treated for Trichomonas	Yes	2.33 (1.46, 3.71)
Used Condoms w/ Vag Sex	Yes	0.43 (0.27, 0.69)
Less Likely to use Alcohol before Sex	Yes	0.63 (0.44, 0.91)

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 - Penile swabs compared to urines
- Repeat tests data for females
- Male trichomonas paper

ORIGINAL ARTICLE

Trichomonas vaginalis infection in men who submit self-collected penile swabs after internet recruitment

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ABSTRACT

Background Submission of self-collected penile samples collected at home could remove barriers that men face in getting tested for sexually transmitted infections (STIs).

Methods From December 2006 to July 2012, sexually active men aged ≥ 14 years were recruited by an educational internet program (<http://www.iwanthekit.org>) which offered free testing for *Trichomonas vaginalis* infection. Kits were ordered online and swabs were sent via US mail to the laboratory and tested by nucleic acid amplification tests. Demographics and sexual risk factors were accessed by questionnaires. Men called or were contacted to receive their results. Risk factors for trichomonas infection were determined by multivariate logistic regression.

Results Of 4398 men requesting kits, 1699 (38.6%) returned swabs by mail (55.4% returned in 2012). Forty-one percent of men were aged <25 years, 43% were black subjects and 45% were white. The overall prevalence for trichomonas in the 1699 men was 3.7%; the highest prevalence by age group was for men aged 40–49 years (5.2%) and, by year, 216 men screened in 2008 had the highest prevalence (12.5%). Risk factors for 919 men whose risk information was collected by questionnaire (prevalence 6.0%) indicated that 9.6% had a concurrent chlamydia infection. Significantly associated risks factors included: black race (adjusted OR 2.67), residence in Illinois (OR 12.02), age 30–39 years (OR 6.63) and age >40 years (OR 5.31).

Conclusions A fairly high prevalence of trichomonas and sexual risk factors were demonstrated from internet recruitment of men. This method of engaging men to get screened for trichomonas may augment screening in STI clinics.

of 11% compared with 1.6% in Hispanic subjects and 1.5% in white women.⁵ The National Health and Nutrition Examination Survey (NHANES) 2001–2004 estimated that 3.1% of women in the USA have TV.⁷ Data from NHANES also demonstrated that TV was associated with other STIs among women in the civilian US population in a sample of 3648 women representing a weighted sample of the experience of 65 563 298 women aged 14–49 years.⁸ The prevalence of trichomoniasis was 3.2%, with $>80\%$ of cases being asymptomatic. Public health wisdom assumes that men are the reservoir for trichomonas infections in women and vice versa.

More data and improved methods are needed to screen men for trichomonas. Submission of self-obtained penile samples collected at home could increase screening, as well as removing barriers that men face in getting tested for STIs. The purpose of this study was to provide trichomonas testing by nucleic acid amplification tests (NAATs) in men using self-collected penile-meatal swabs after internet recruitment to determine the prevalence and to ascertain risk factors associated with trichomoniasis.

METHODS

Sexually active men aged ≥ 14 years were recruited by an internet program (<http://www.iwanthekit.org>) which was educational for STIs and offered free testing from self-collected penile-meatal samples for trichomonas, chlamydia and gonorrhea from December 2006 to July 2012. Specific directions for sample collection were provided in each kit and on the website. The study was approved by the Institutional Review Board (IRB) with written

Trichomonas Prevalence in Males

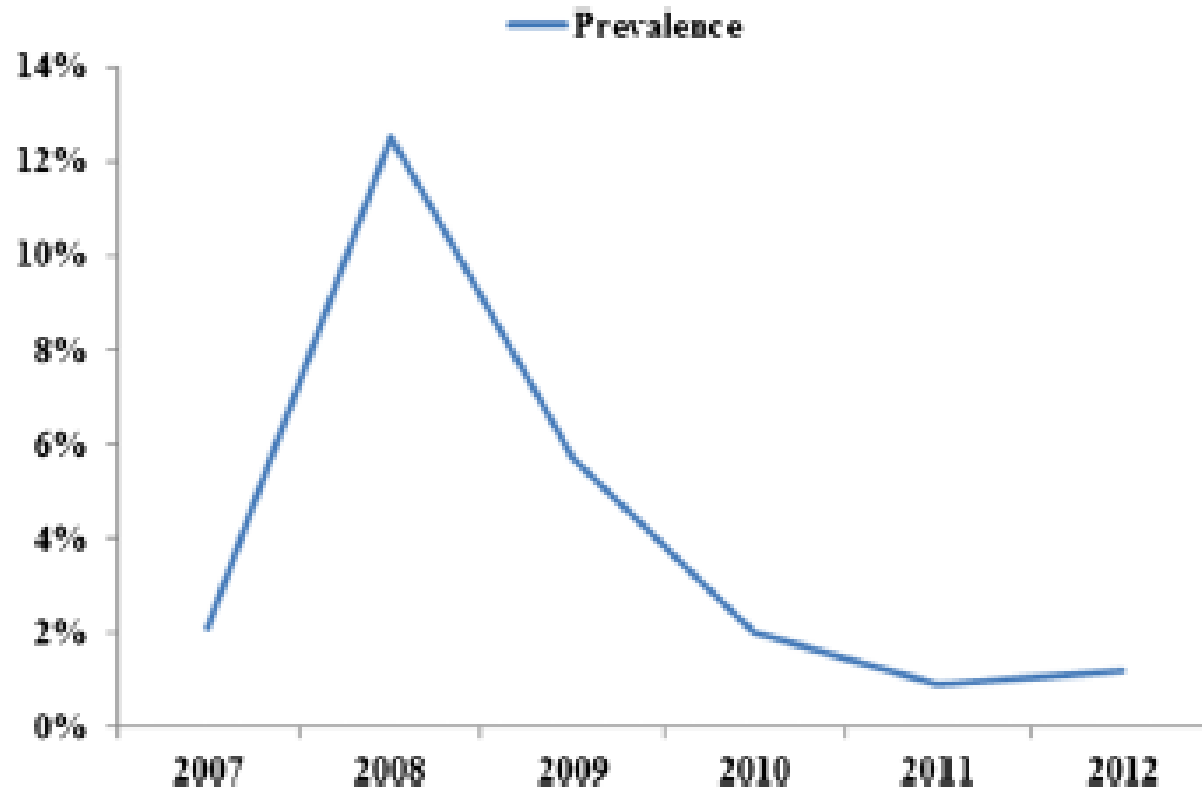


Figure 1 Prevalence of *Trichomonas vaginalis* infection in 1699 men who participated in the internet screening program.

Summary

- STDs common: prevalent, incident, young & old
- High risk scores predicts high prevalence
- Recent papers published: Penile swabs, Dry swabs, Repeat tests, Cost-effectiveness, Male trichomonas
- Lack of consent form increased return rate
- IWTK website being modernized

CT, NG, TV



CT, NG, TV +
Self HIV POC &
TV POC

Acknowledgements

Mathilda Barnes, MS

Yu-Hsiang Hsieh, PhD

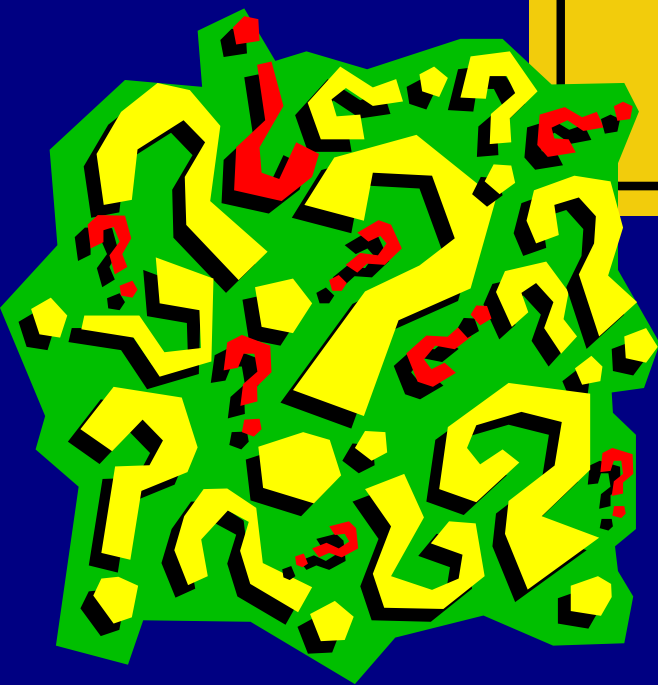
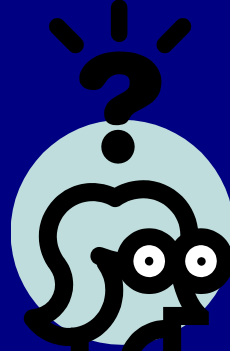
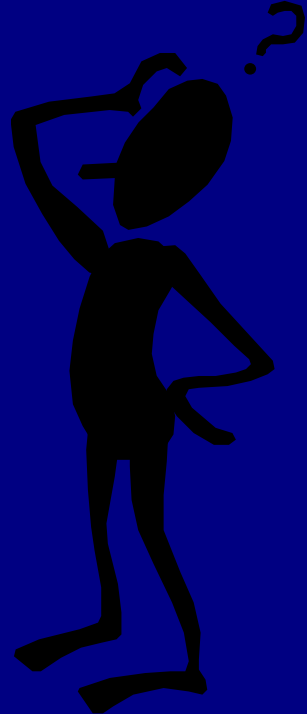
Nicole Quinn, BS

Pamela Whittle, BS

Mary Jett-Goheen, BS

Perry Barnes, BS

Terry Hogan, MPH



Repeat Male Tests on the Internet

- Men: (N=852)

115 (13.5%) of men have used the Internet previously during 2007-2010

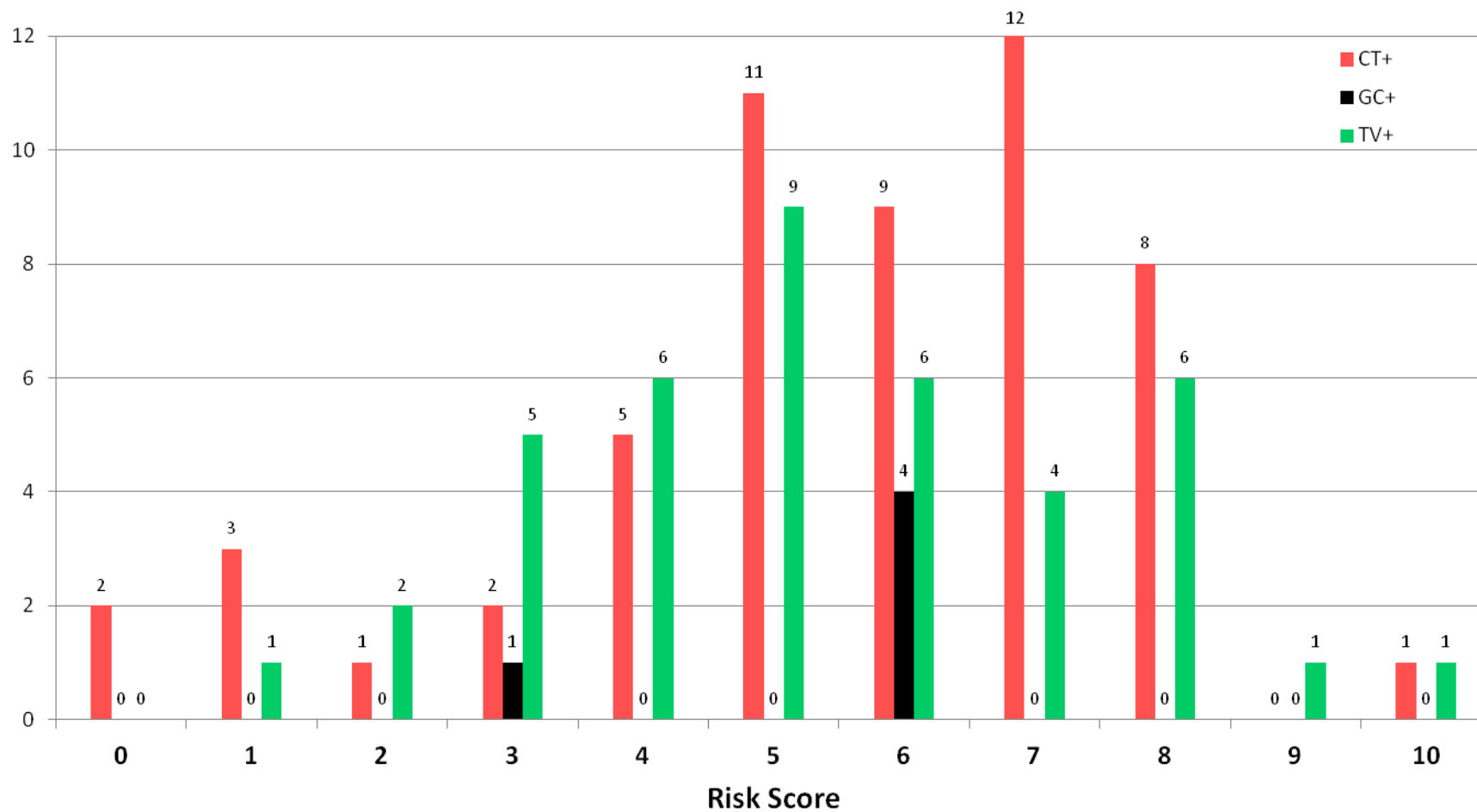
- Of these:

1 more time	53.0%
2-5 times	39.1%
> 5 times	4.3%
Missing:	3.5%

Repeat Male Tests on the Internet

	Previous Prevalence	Current Prevalence
Ct	9.6%	16.5%
GC	3.5%	2.6%
TV	7.0%	4.3%
Any	19.1%	20.9%

IWTK – Individual Risk Scores & Returned/Tested Kits with Positive Results - Male & Female Combined



I Want the Kit – Website Hits

Year	Jan	Feb	Mar	April	May	June	July	Aug	Sept	Oct	Nov	Dec
2008	55,197	47,260	45,115	49,391	52,679	51,553	52,870	46,663	54,807	63,769	53,646	65,486
2009	69,045	68,642	75,299	76,697	69,303	78,504	65,782	65,782	91,281	96,517	87,453	71,442
2010	85,868	75,778	92,334	79,105	81,608	82,515	86,687	82,141	85,090	106,015	98,266	86,552
2011	89,771	291,687	147,601	184,556	102,136	88,820	100,576	109,387	99,602	103,723	88,458	88,389
2012	92,490	90,107	91,191	105,599	90,906	94,716	102,675	98,548	95,192	113,712	113,125	108,881
2013	124,103	98,986	110,951									

- February 2011 = Johns Hopkins University Press Release
- April 2011 = GYT/STD Awareness Month, Social Marketing/Advertising
- May 18, 2011 = City Paper, print advertisement, Sizzlin' Summer issue
- August 24, 2011 = City Paper, print advertisement, College Guide issue
- February 2012 = Facebook advertising in Maryland only
- March 12-15, 2012 = CDC National STD Prevention Conference
- April 2012 – Radio advertising on 92Q
- June 1 – July 21, 2012 – Radio advertising on 92Q
- April 2013 - Radio advertising on 92Q
- (7/2012 – 4/2013 = JHU STS team redesigning website)

Clinic and Focus Group Questionnaire about Near Patient Tests (N =371)

Re-screening Preference	Percent
Home	46.4%
Clinic Screening	47.4%
Private Dr.	6.2%

How Easy or Hard to Collect Vag. Swab	Percent
Very Easy	62.0%
Easy	33.7%
OK	4.0%
Hard	0.0%
Very Hard	0.3%

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